

**Title: The safety and effectiveness of clinical
performance of Breath-O correct orthokeratology
lenses**

(NCT03616600)

Date: 10th March, 2019

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Methods:

Sample size: 15 subjects for each group were recruited

Groups: Treatment group – prescription of Breath-O Correct lens

Control group – non-contact lens wearer

Inclusive criteria:

Age: 18 to 30 years

Refractive error: Spherical: normally -1.00D to -4.00D (maximum up to -5.00D); Cylindrical: normally \leq half of Sph (against-the-rule Astig.: \leq -0.75D) (maximum up to \leq -1.50D)

Best corrected Visual acuity: monocular ETDRS 0.0 or better

Ocular health: No ocular abnormality, no contra-indications for overnight orthokeratology lens wear, no refractive surgery

General health: No systemic diseases

Requirement: No history of orthokeratology lenses wearing. Agree to participate in this study and willing to wear the orthokeratology lenses overnight in accordance with the instructions given and to come back for follow up within the study period

Parameters to be assessed:

Effectiveness: Objective and subjective refractive error, central corneal thickness, high contrast visual acuity, low contrast visual acuity, corneal topography

Safety: Corneal epithelium and endothelium health, corneal resistance factor and corneal hysteresis, tears quality.

Subjective evaluation: OSDI Questionnaire

Analysis: Categorical variables were presented as number or percentage, while continuous variables were presented as mean and standard deviation. Data from both eyes of each subject were analyzed for follow-up visits (within subjects) and for group comparison (between groups). RM-ANOVA, 2-way ANOVA and Friedman test were used for comparison. The significance level is set at $p < 0.05$.

Protocol:

- All the subjects had a baseline eye examination with all the above tests. A written consent was obtained from each eligible subject before randomly allocating into treatment group (fitting of the contact lenses) or control group (no fitting of contact lens)
- A pair of Breath-O Correct lenses were prescribed for each eligible subject of the treatment group with full wearing instructions of orthokeratology
- After successful prescription of the lenses, the subjects of the treatment group came back for regular visits listed in Figure 1
- For the subjects of the control group, all had the eye examination same as those received by treatment group at the time point of baseline, 1st month and 3rd month.

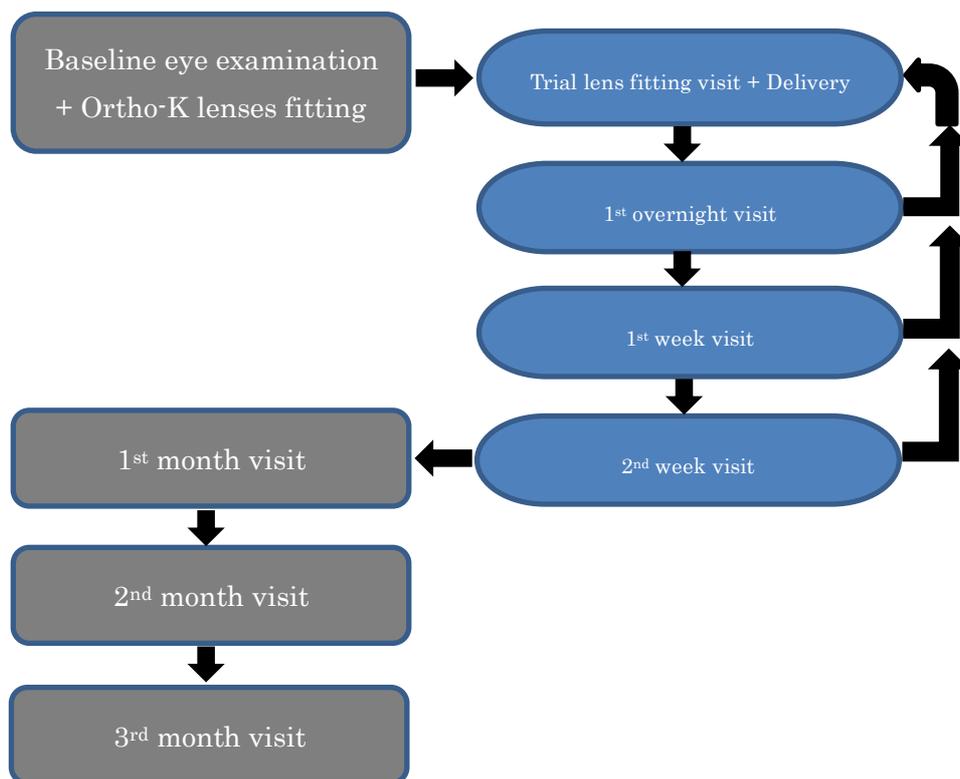


Figure 1. Schedule of visits